## Mail Stop Amendmen

Attorney Docket No. 25871



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re Application of:

Daniel J. Thompson et al.

Group Art Unit: 1614

Serial No.: 10/767,431

Examiner: Unknown

Filed:

January 30, 2004

Title:

METHOD OF TREATMENT OF CANDIDA ISOLATES

#### TRANSMITTAL LETTER

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office are the following:

- (1) Transmittal Letter;
- (2) Information Disclosure Statement;
- (3) PTO Form 1449 listing twelve (12) references; and
- (4) Copies of eight (8) literature references.

The Commissioner is hereby authorized to charge any fee deficiency to Deposit Account No. 14-0112.

Respectfully submitted,

NATH & ASSOCIATES PLLC

By:

Gary M. Nath

Registration No. 26,965

Tanya E. Harkins

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Customer No. 20529

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#### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. §1.97-1.98. Please note the following particulars:

[NOTE: One only of items a, b, c, and d must be checked.]

- [ X ] a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. §1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.
- [ ] b. The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. §1.113, or a notice of allowance under 37 C.F.R. §1.311.

The enclosed statement is accompanied by [check one]:

- [] i. a certification in part (e) below as specified in 37 C.F.R. §1.97(e), or
- [] ii. a check in the amount required by 37 C.F.R. § 1.17(p).
- [ ] c. The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. § 1.113, or a notice of allowance under 37 C.F.R. § 1.311, but before payment of the issue fee.
  - [ ] Certification report(e) below; and
  - [ ] a check in the amount as required by § 1.17(p).
- [ ] d. The enclosed statement is being filed pursuant to 37 C.F.R. § 1.97(i), for placement in the file.
- [ ] e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]

[ ] I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

] I hereby certify that no item of information in the enclosed ſ Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

- ] Appropriate certification is attached.
- [X]f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.
- [ **X** ] g. Copies of the literature documents are attached herewith with a completed Form PTO-1449.

[ **X** ] Copies of the documents are not attached as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as: or Copies of US Patents/Publications not attached as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,

NATH & ASSOCIATES PLLC

By:

M. Nath

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# FORM PTO-1449 MATION DISCLOSURE CITATION

Atty Docket Serial No.
25871 10/767,431

Applicant
Daniel Thompson et al.

Filing Date Group Art Unit January 30, 2004 1614

			U.S. PAI	ENT DOCUMENTS				
Examiner Initial		Document Number	Issue Date	Name	Class	Sub- Class	Filing Date	
	A	4,078,071	03/07/78	Walker			01/10/77	
	В	4,551,148	11/05/85	Riley, Jr. et al.			10/11/84	
	С	4,636,202	01/13/87	Lowin et al.			07/27/84	
	D	5,266,329	11/30/93	Riley, Jr.			06/12/87	
	E							
			FOREIGN PA	ATENT DOCUMENTS				
		Document Number	Date	Country	Class	Sub- Class	Trans- lation	
	F							
	G				_			
	Н	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)  Brown, Dale et al. Butoconazole nitrate 2% for vulvovaginal candidiasis. J. Reprod. Med. (1999) 44(11):933-938.  Cross, Emily W. et al. Cross-Resistance of Clinical Isolates of Candida albicans and Candida glabrata to Over-The-Counter Azoles Used in the Treatment of Vaginitis. Microbial Drug Resistance. (2000) 6(2): 155-161.  Fiesco, A. et al. Efficacy of butoconazole nitrate in the treatment of						
W.R.	J	vulvo-vaginal candidiasis compared with clotrimazole and isoconasol.  Proc. West. Pharmacol. Soc. (1993) 36:185-188.						
	K	Gynazol-1® product insert and website printout of product information.						
	L	Lynch, M.E. and Sobel, J.D. Comparative in vitro activity of antimycotic agents against pathogenic vaginal yeast isolates. Journal of Medical and Veterinary Mycology (1994) 32: 267-274.						
	М	Sobel, JD. Vaginitis. N Engl. J. Med. (1997) 337(26):1896-1903.						
	N	Terazol® 7 Terazol® 3 pages.	Terazol® 7 vaginal cream 0.4%, Terazol® 3 vaginal cream 0.8%, and Terazol® 3 vaginal suppositories 80mg prescribing information. 2 pages.					
	0	cream: com	L et al. Va parison of a . (1994) 16(	ginal retention of 2% be standard and a sustain 6):930-934.	outoconaz ned-relea	ole nita se prepa	rate aration.	

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to Applicants.